

REMARKS/ARGUMENTS

Claims 16, 19, 20, 22-27, 31, 32, and 36-53 are pending in this application. Claims 1-15, 17-18, 21, 28-30, 33-35, and 54 have been previously canceled.

In the Office Action dated January 28, 2008, the Office stated on page 3 under the heading "Response to Arguments" that "Applicant's arguments with respect to claims 16, 19, 20, 22-27, 31, 32 and 36-53 have been considered by are moot in view of the new ground(s) of rejection." Applicants respectfully point out that no arguments were presented regarding claims 16, 22-27, 31, 32 and 36-53 because in the previous Office Action, dated October 1, 2007, the Office stated that claims 23-27, 31, 32, and 36-51 were allowed and that claims 19 and 20 were allowable if re-written in independent form. In the October 1, 2007 Office Action, the Office stated "[t]he prior art does not disclose, teach or suggest a method of administering to a patient microparticles comprising diketopiperazine and an active agent. It is not disclosed, taught or suggest to formulate the microparticles comprising the polymers in claims 30, 32 and 50. It is also not taught to use add a diketopiperazine compound to the particles." Claims 16, 22-27, 31, 32 and 36-53 have not been amended since October 1, 2007 which could have necessitated a new search and/or new grounds of rejection. Therefore, Applicants are unclear about the additional search and rejections that were made in the Office Action dated January 28, 2008. However, Applicants have addressed the rejections presented in the January 28, 2008 Office Action in good faith.

Claims 27, 32 and 50 have been amended as discussed *infra*. No new matter has been introduced as a result of the claim amendments.

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

35 U.S.C. §112 Rejection

Claims 27, 31, 32, 36, 50 and 51 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention. It was unclear to the Office what the term copolymers in claims 27, 32 and 50 comprise.

Claims 27, 32 and 50 have been amended to indicate that the microparticles consist essentially of the therapeutic, prophylactic or diagnostic “and a polymer or co-polymer comprising at least one material selected from the group consisting of poly(hydroxy acids), polyanhydrides, polyesters, polyamides, polycarbonates, polyalkylenes, polyvinyl compounds, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, poly(butyric acid), poly(valeric acid), poly(lactide-co-caprolactone), and polysaccharides, ~~and copolymers~~ and mixtures thereof.”

In view of the amendments to claims 27, 32 and 50, Applicants request the withdrawal of the rejection under 35 USC §112, second paragraph of claims 27, 31, 32, 36, 50 and 51.

35 U.S.C. §103 Rejection

It is well established that a *prima facie* case of obviousness requires that the Office provide evidence to support three basic criteria: there must be some suggestion or motivation in the cited art to modify a reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all the claim limitations. MPEP 2143.

Moreover, Office is respectfully reminded of the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993) see also *Takeda Chemical Industries, Ltd. v. Alpharma Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

Also, the Office is respectfully reminded that for the 35 U.S.C. §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicant's disclosure. *In re Dow*, 5 U.S.P.Q. 2d 1529, 1531 (Fed.Cir. 1988).

Claims 16, 19, 20, 22, 27, 32, 37, 38, 39 and 50-53 have been rejected under 35 USC §103(a) as being unpatentable over Debenedetti et al. (US 6,063,910) or Sugaya et al. (JP 363020301A) in view of Hunt et al. (US 4,866,061).

The Office states on page 4 of the Office Action dated January 28, 2008 that Debenedetti teaches forming protein microparticles having a particle size less than 10 microns. The Office additionally states that Sugaya discloses highly pure microparticles of chitosan having an average particle diameter of less than 10 microns. On page 5 under the heading "Ascertainment of the difference between the prior art and the claims," the office states "Debenedetti et al. or Sugaya et al. do not disclose the microparticle releasing a drug at a pH of 6.0 or greater or that the particles are stored in a cartridge for insertion into an inhaler. It is for this that Hunt et al. is joined." The Office cites column 3, lines 23-37 of Hunt et al. for teachings of the use of inhalation cartridges with particles having a size below 10 microns. However, Hunt et al. does not disclose a microparticle releasing a drug at a pH of 6.0 or greater.

Applicants respectfully assert that the Office has not established *prima facie* obviousness of the instant claims over the combination of Debenedetti et al. or Sugaya et al. in view of Hunt et al. because the combination of the three references do not teach or suggest each and every element of the instant claims. None of the three references teach or suggest a microparticle releasing a drug at a pH of 6.0 or greater. Furthermore, Applicants respectfully assert that there is no motivation to combine the references because Hunt et al. teaches microparticles comprising an active agent only and not microparticles comprising an active agent and a polymeric material. Therefore there is no motivation to combine the teachings of Hunt et al. with those of Debenedetti et al. or Sugaya et al., both of which teach microparticles comprises of a polymeric material and an active agent.

As such, the Office has not established *prima facie* obviousness of claims 16, 19, 20, 22, 27, 32, 37, 38, 39 and 50-53 over the combination of Debenedetti et al. or Sugaya et al. in view of Hunt et al. and therefore, Applicants respectfully request the Office withdraw the rejection under 35 USC §103 of the instant claims.

Claims 23-26 and 40-49 have been rejected under 35 USC §103(a) as being unpatentable over Cheatham et al. (US 2005/0153874).

The instant application has a filing date of November 12, 2003 and claims priority through a series of continuation applications to May 15, 1995. The application to Cheatham was filed on January 10, 2005 and claims priority to January 12, 2004. Therefore, because it has a filing date after both the filing date and the priority date of the instant application, Cheatham is not prior art to any of the claims in the instant application. Applicants respectfully request the withdrawal of the rejection under 35 USC §103(a) of claims 23-26 and 40-49.

Conclusions

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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